IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES LLC, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. 12-23 (GMS)
v.	)	REDACTED - PUBLIC VERSION
MEDTRONIC COREVALVE LLC, *et al.*,	)	
Defendants.	)	

EDWARDS' OPENING BRIEF IN SUPPORT OF ITS MOTION FOR ATTORNEYS' FEES PURSUANT TO 35 U.S.C. § 285

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I. NATURE AND STAGE OF THE PROCEEDINGS

This case is exceptional. Edwards[1] was forced to bring this lawsuit due to Medtronic's[2] failure to cease its infringing activities. Almost four years ago, on April 1, 2010, CoreValve, Inc., and Medtronic CoreValve, LLC were found to have willfully infringed Edwards Lifesciences AG's Andersen '552 Patent.[3] Post-verdict Medtronic assured this Court that it was moving its manufacturing operations offshore to Mexico. Yet, Medtronic failed to do so. And, from the recent trial testimony, it is clear that even as Medtronic was filing briefs telling the Court it was moving, it had no intention of moving all of its operations to Mexico. This, combined with Medtronic's practice of repeatedly ignoring several Court Orders and taking legally unsupportable positions, has served only to increase the litigation costs incurred by Edwards. An award of attorneys' fees is appropriate here.

On January 15, 2014, the jury returned a verdict that Medtronic had literally and willfully infringed the Cribier '825 Patent[4] owned by Edwards. [D.I. 170 at 2-5]. The jury rejected Medtronic's invalidity defenses of lack of written description, non-enablement, and obviousness. [*Id.* at 6-8]. The jury awarded Edwards lost profits of $388.8 million and a reasonable royalty of $4.8 million. [*Id.* at 9]. Judgment was entered

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1 "Edwards" refers to Edwards Lifesciences LLC and Edwards Lifesciences PVT Inc.

2 "Medtronic" refers to Medtronic CV Luxembourg S.a.r.l., Medtronic CoreValve LLC, Medtronic, Inc., Medtronic Vascular Galway Ltd., and Medtronic Vascular Inc.

3 As used herein, " '552 Patent" refers to U.S. Patent No. 5,411,552.

4 The " '825 Patent" refers to U.S. Patent No. 8,002,825.

on January 27, 2014. [D.I. 176]. Edwards now moves for attorneys' fees and related expenses under 35 U.S.C. § 285.[5]

II. SUMMARY OF ARGUMENT

Edwards respectfully requests that the Court declare this an exceptional case and award attorneys' fees and related expenses pursuant to 35 U.S.C. § 285. The Court's January 27, 2014 Judgment in favor of Edwards, [D.I. 176], qualifies Edwards for such award. *See* 35 U.S.C. § 285 ("The court in exceptional cases may award reasonable attorney fees to the prevailing party").

Edwards' request requires the Court to determine "whether there is clear and convincing evidence that the case is 'exceptional,' and if so, whether an award of attorney fees to the prevailing party is warranted." *Interspiro USA, Inc.* v. *Figgie Int'l Inc.*, 18 F.3d 927, 933-34 (Fed. Cir. 1994); *see, e.g.*, *Trueposition Inc.* v. *Andrew Corp.*, 611 F. Supp. 2d 400, 414 (D. Del. 2009) (granting attorneys' fees motion and then requesting documentation of reasonable amount).[6] Here, the answer to both questions is yes. For reasons that follow and pursuant to Federal Rule of Civil Procedure 54(d)(2)(B)(iii), Edwards seeks an estimated $8.88 million in fees and expenses.[7]

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[5] On January 27, 2014, the Court Ordered that Plaintiffs' post-trial motions be filed by March 17, 2014, thus extending the 14 day provision of Fed. R. Civ. P. 54(b). [D.I. 178].

[6] An award of attorneys' fees is a two-step process. First a court must determine that an award is warranted; next it must calculate a reasonable amount. *See, e.g.*, *TruePosition*, 611 F. Supp. 2d at 414, *aff'd*, 389 Fed. App'x 1000 (Fed. Cir. 2010). This opening brief canvasses only the reasons why an award is justified in this case.

[7] This amount covers estimated attorneys' fees and expenses, including expert expenses, through trial. *See* Fed. R. Civ. P. 54(d)(2)(B)(iii) (motion for attorneys' fees should "state the amount sought or provide a fair estimate of it"). Edwards reserves its rights to seek fees and costs associated with post-trial motions yet to be decided and any appeals.

An award of attorneys' fees and expenses is warranted in this case because:

1. Medtronic forced Edwards to litigate this case, at great expense, due to its failure to move its operations to Mexico following the April 1, 2010 jury verdict of willful infringement of Edwards' Andersen '552 Patent. This, despite Medtronic's repeated representation to multiple courts, the public, and Edwards that it would relocate the manufacture of the CoreValve device offshore and thereby cease its U.S. operations. Medtronic concealed the extent to which it maintained key manufacturing processes inside the United States at great expense to Edwards;

2. Medtronic willfully infringed Edwards' patent and had no good faith basis to believe its actions did not constitute infringement;

3. Medtronic engaged in bad faith litigation and litigation misconduct through its repeated disregard of the Court's Orders and claim construction; and

4. The *Read* factors support an award of attorneys' fees and related expenses.[8]

III. STATEMENT OF FACTS

The relevant facts are set forth in the Argument section below.

IV. ARGUMENT

In an exceptional case, the Court may award reasonable attorneys' fees to the prevailing party. 35 U.S.C. § 285. An exceptional case may be established "when there has been some material inappropriate conduct related to the matter in litigation,"

[8] *See Read Corp.* v. *Portec, Inc.*, 970 F.2d 816, 825-27 (Fed. Cir. 1992).

including (1) willful infringement; (2) litigation misconduct; or (3) vexatious, unjustified, and otherwise bad faith litigation. *Brooks Furniture Mfg.* v. *Dutailier Int'l, Inc.*, 393 F.3d 1378, 1381 (Fed. Cir. 2005). As described below, Medtronic engaged in each of these types of conduct. In addition, in determining whether a case meets the threshold required under 35 U.S.C. § 285, courts consider the factors relevant to an enhanced damages award, also known as the "*Read* factors." *E.g.*, *Lucent Tech., Inc.* v. *Newbridge Networks Corp.*, 168 F. Supp. 2d 269, 276 (D. Del. 2001) ("Based on the jury's finding of willfulness and the factors discussed in the context of the Court's enhanced damages determination, the Court concludes that the instant case is exceptional, such that [plaintiff] is entitled to an award of reasonable attorneys' fees.") Here, application of the *Read* factors cements the conclusion that this is an exceptional case for which attorneys' fees should be granted.

A. Edwards Was Forced to Litigate, at Great Expense, Medtronic's Infringement of the '825 Patent Because Medtronic Failed to Honor Its Promise to Move Operations to Mexico

Nearly four years before the jury found that Medtronic's manufacture and sale of the CoreValve device constituted willful infringement of Edwards' '825 Patent, *see* [D.I. 170], a different jury found that Medtronic's manufacture and sale of the same CoreValve device constituted willful infringement of Edwards' '552 Patent. *See Edwards Lifesciences AG* v. *CoreValve, Inc.*, No. 08-091 (GMS) (D. Del.) ("*Edwards I*") [D.I. 313 at 2-4]. Litigating the '825 Patent would not have been necessary had Medtronic completely moved its CoreValve manufacturing operations to Mexico, as it had represented it would after *Edwards I*. But Medtronic's failure to follow through on its promised offshoring, and the litany of misleading statements it made to conceal this

fact,[9] forced Edwards to incur substantial costs in defending its intellectual property rights against the same product for a second time.

On April 1, 2010, the same day the *Edwards I* verdict was announced, Medtronic issued a Press Release stating "In the event of an injunction, Medtronic has manufacturing capabilities for CoreValve products outside the United States to ensure continued supply world wide." Declaration of Jeremy A. Benjamin in Supp. of Edwards' Mot. for Att'y Fees Pursuant to 35 U.S.C. § 285 ("Decl."), Ex. A. This was the first official statement from Medtronic indicating that rather than design around the '552 Patent, Medtronic would move its CoreValve manufacturing operations offshore to avoid liability under United States patent laws.[10] Medtronic reiterated this position to this Court. *See Edwards I*, [D.I. 429 at 27-29]; *id.*, [D.I. 392 at 6 (claiming that Medtronic was "setting up alternative manufacturing facilities in Mexico" that would match current Irvine production by mid-2011)].

[redacted]

[9] *See* Opening Br. in Supp. of Edwards Mot. For Permanent Injunction, App. A, filed herewith.

[10] The financial community clearly understood these statements to mean that Medtronic was moving to Mexico. *See, e.g.*, Decl., Ex. B at 1 ("MDT [Medtronic] is in the process of moving manufacturing for CoreValve's European business to Mexico.")].

[redacted]

Sixteen months after the jury's verdict in *Edwards I*, the'825 Patent issued. *See* Decl., Ex. E. During that time, Medtronic had not ceased the sale and manufacture of the CoreValve product; nor moved its manufacture entirely offshore. Instead, it continued to manufacture CoreValve devices in the United States; supplied from the United States to Mexico a substantial portion of the components of the

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11 [redacted]

12 [redacted] Seeing through Medtronic's circular argument, the Federal Circuit emphasized that the denial of injunctive relief hinged, in large part, on Medtronic's statements that it *was moving* operations offshore. *Edwards*, 699 F.3d at 1315. The Federal Circuit admonished: "Whether or not that representation was known to be false when made, the situation before us reflects, at least, changed circumstances." *Edwards*, 699 F.3d at 1315. It then vacated the denial of Edwards' injunction motion. *Id.* at 1315-16. This motion remains pending in *Edwards I*. *Edwards I*, [D.I. 464].

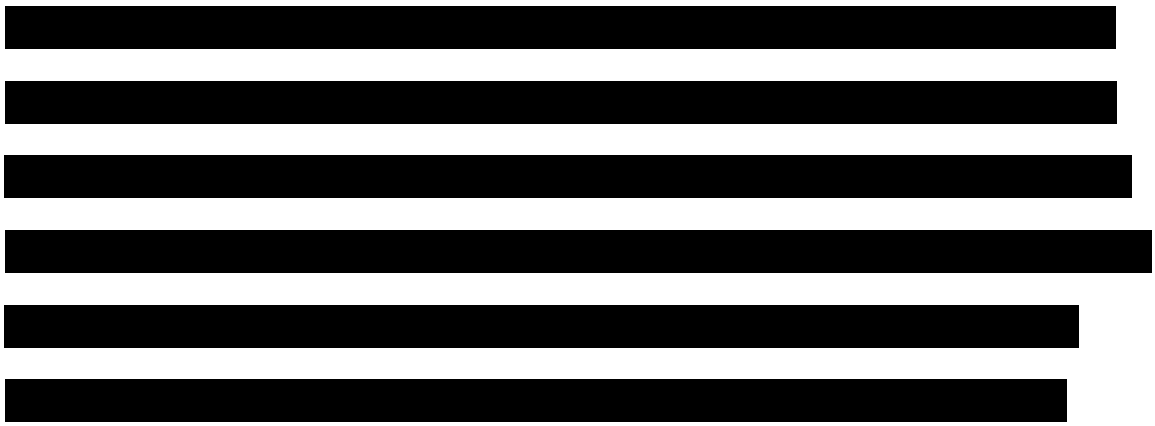
CoreValve device to Mexico with the intent that they be combined there to form the infringing device; and supplied from the United States to Mexico components that are especially made or especially adapted for use in the CoreValve device and that are not staple articles of commerce. *See* [D.I. 170 at 2-4].

[redacted] When Edwards was faced with a retaliatory action filed against it by Medtronic,[13] Edwards counterclaimed in September 2011, *inter alia*, that Medtronic's supply of components from the United States to Mexico for manufacture of the CoreValve device constituted infringement of the '825 Patent under 35 U.S.C. § 271(f). *See California Action*, [D.I. 27].[14]

[13] Medtronic's allegations that Edwards infringed U.S. Patent No. 7,892,281 were dismissed on summary judgment. *See Medtronic CoreValve LLC* v. *Edwards Lifesciences Corp.*, Case No. 8:11-961 (JVS-MLG), [D.I. 162, 163] (C.D. Cal. 2011) ("*California Action*"), *aff'd* 741 F.3d 1359 (Fed. Cir. 2014). Medtronic's motion for rehearing is pending. *Medtronic CoreValve LLC* v. *Edwards Lifesciences Corp.*, Case No. 2013-1117, [D.I. 55], (Fed. Cir.).

[14] The California district court transferred Edwards' counterclaim to this Court, where it was filed as a stand-alone complaint. *California Action*, [D.I. 69]; [D.I. 2]. Edwards has filed a related complaint in this Court against Medtronic concerning the '552 Patent, among others, and Medtronic's supply of components from the United States to Mexico for the assembly of the CoreValve device. *Edwards Lifesciences AG et al.* v. *Medtronic Inc. et al.*, 09-873 (GMS) (D. Del.) [D.I. 1]. That case remains pending.

Throughout the '825 Patent litigation, discerning and proving the extent to which Medtronic *had not moved* its manufacturing operations offshore remained a central focus. *See, e.g.*, [D.I. 44 (listing several Rule 30(b)(6) topics directed at infringement under 35 U.S.C. § 271(f))]; Decl. Ex. G at 7-8 (interrogatories concerning infringement under 35 U.S.C. § 271(f)); [D.I. 77 (seeking to amend complaint to make clear Edwards was seeking a liability determination under 35 U.S.C. § 271(f))]; [D.I. 111 at ¶¶ 13-15 (Allegations directed at 35 U.S.C. § 271(f) infringement]; [D.I. 150 (Order denying *in limine* motion relating to the admissibility of evidence the pericardial sacs and coupons are not "components" under 35 U.S.C. § 271(f)]; [D.I. 157 at 4-9 (seeking to preclude evidence of damages related to 35 U.S.C. § 271(f) liability)]; [D.I. 170 at 3-4 (finding liability under 35 U.S.C. § 271(f)(1) and 35 U.S.C. § 271(f)(2)]. Discovery revealed that Medtronic continued to supply from the United States to Mexico a substantial portion of the components of the CoreValve device with the intent that they be combined there to form the CoreValve device; and components that were especially made or especially adapted for use in the CoreValve device that are not staple articles of commerce. In light of this evidence—and Medtronic's attempts to conceal it, *see, e.g.*, Decl., Ex. H at 2—



[redacted]

At trial, Edwards proved these facts. For example, David Montecalvo, Medtronic's global vice president of operations for the structural heart business, admitted that even today, Medtronic manufactures entire CoreValve devices in Irvine. Decl., Ex. J at 1014:21-1015:20. Mr. Montecalvo acknowledged that maintaining a presence in Irvine was always part of Medtronic's plan. *Id.* at 1022:18-1023:21, 1025:16-1026:1. And, he agreed that the tissue harvesting and fixation processes, which is performed

exclusively in the United States, are important steps in manufacturing the CoreValve. *Id.*, at 1017:11-21.

The jury recognized that Medtronic's partial relocation of its manufacturing operations was insufficient to escape liability under U.S. patent law. But establishing Medtronic's willful infringement (yet again) was costly. Given the history recounted above, Medtronic should be made to pay those costs, which could have been avoided had Medtronic respected the verdict in *Edwards I*.

B. There Was Willful Infringement

The evidence at trial was clear and convincing: Medtronic had willfully infringed the '825 patent. [D.I. 170 at 5]. The jury recognized that there was an "objectively high likelihood" that Medtronic's actions were infringing, and that Medtronic knew or should have known of that objectively high risk. *See* [D.I. 168 at 32]; [D.I. 170 at 5]. The resulting willful infringement verdict alone supports finding this case exceptional resulting in an award of attorneys' fees. *See Golight* v. *Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1340 (Fed. Cir. 2004) (citing *Avia Grp. Int'l, Inc.* v. *L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1567 (Fed. Cir. 1988)). "Cases of willful infringement often qualify for [attorneys'] fee awards." *Fisher-Price, Inc.* v. *Safety 1st, Inc.*, Civ. A. No. 01-051 (GMS), 2008 WL 1976624, at *7 (D. Del. May 5, 2008). Indeed, "[a]n award of attorneys' fees and costs is typical in cases of willful infringement." *Advanced Med. Optics, Inc.* v. *Alcon Labs., Inc.*, Civ. A. No. 03-1095 (KAJ), 2005 WL 3454283, at *10 (D. Del. Dec. 16, 2005) (awarding "reasonable attorneys' fees and costs" because of "evidence of willful infringement"); *C.R. Bard, Inc.* v. *U.S. Surgical Corp.*, 258 F. Supp. 2d 355, 363 (D. Del. 2003) ("[T]he Court, in view of the jury's finding of willful

infringement finds this case to be 'exceptional' and awards attorneys' fees and costs."). Combining the jury's willfulness finding with Medtronic's behavior since 2010, which made this lawsuit necessary, strongly supports an award of attorneys' fees and related expenses.

C. Medtronic's Litigation Conduct Supports an Award of Attorneys' Fees and Related Expenses

Medtronic's repeated attempts to present evidence and make arguments contrary to the Court's claim construction Order, [D.I. 103], and Orders concerning the parties' motions *in limine, see* [D.I. 139]; [D.I. 150], warrants an award of attorneys' fees and related expenses. *See, e.g.*, *Takeda Chem. Indus.* v. *Mylan Labs.*, 549 F.3d 1381, 1385, 1390-1391 (Fed. Cir. 2008) (affirming $16.8 million award of attorneys' fees, expenses, and expert fees based on conduct of defendants during litigation); *see also* Pls.' Opening Br. in Supp. of Their Motion for Enhanced Damages Pursuant to § 284 at 7-9.

[redacted] Medtronic persisted in creating demonstratives, arguing in opening statements, and questioning witnesses to advance this argument. *See, e.g.*, Decl., Ex. J at 4:20-13:4; 190:22-191:14; 288:2-24; 326:10-328:17. Additionally, Medtronic objected to jury instructions that would clarify that these tactics were irrelevant and contrary to the Court's construction. *Id.* at 1287:9-1290-3. As Medtronic's renewed motion for JMOL demonstrates, even post-verdict, Medtronic will not accept the Court's rulings. *See, e.g.*, [D.I. 184 at 1-14]. Medtronic's repeated failure to obey the Court's Order supports an award of attorneys' fees and related expenses. *See*

i4i Ltd. P'ship v. *Microsoft Corp.*, 598 F.3d 831, 859 (Fed. Cir. 2010) ("Typically, 'litigation misconduct' refers to bringing vexatious or unjustified suits, discovery abuses, failure to obey orders of the court, or acts that unnecessarily prolong litigation.").

Medtronic also repeatedly disregarded another ruling by the Court, this one prohibiting it from arguing that the pericardial sacs shipped from the United States were not "components" of the CoreValve device. *See* [D.I. 150 (the "treated porcine pericardial sacs . . . that Medtronic supplies form the United States to Mexico . . . are components for the purposes of Section 271(f))]. Medtronic's attempt to circumvent that Order was most pronounced in its cross-examination of Dr. Buller. There, Medtronic's counsel suggested that the pericardial sacs shipped to Mexico were not components of the CoreValve device. Decl., Ex. J at 665:15-24. At sidebar, Medtronic argued that its questioning was entirely proper, claiming that the very issue decided by the Court—whether the porcine pericardial sacs are components for purposes of § 271(f)—was a question for the jury to decide. *Id.* at 666:12-22. On this point, Medtronic's misconduct was not limited to the courtroom. In its Motion to Limit the Damage Demand—filed even as the parties were negotiating jury instructions—Medtronic argued that the jury should not be allowed to decide liability under § 271(f)(1) because "export of the sac, *even if it were a component* of the claimed invention, is only a single supplied component and thus no liability attaches." [D.I. 157 at 4 (emphasis added)]. The emphasized text again indicates Medtronic's unwillingness to accept the Court's Orders and relentless attempt to reargue issues it previously, and decisively, lost. This litigation misconduct supports an award of attorneys' fees. *See Takeda*, 549 F.3d at 1389 (affirming award of

attorneys' fees in part because one of defendant's defenses "was 'always frivolous' and unsupported").

D. The *Read* Factors Support an Award of Attorneys' Fees and Related Expenses

In Edwards' Enhanced Damages Brief, incorporated by reference, Edwards analyzed in detail the factors that support an award of enhanced damages, also known as the "*Read* factors." *Read Corp.*, 970 F.2d at 826-27. The *Read* factors also support an award of attorneys' fees and related expenses. *nCUBE Corp.* v. *SeaChange Int'l, Inc.*, 313 F. Supp. 2d 361, 391 (D. Del. 2004) (awarding attorneys' fees "[b]ased on the jury's finding of willfulness and the factors discussed in the context of the Court's enhanced damages determination"); *Advanced Med. Optics*, 2005 WL 3454283, at *10 (same). Here too, the *Read* factors weigh in favor of an award of attorneys' fees and related expenses.

V. CONCLUSION

Edwards requests that the Court declare this case "exceptional" within the meaning of § 285 and award Edwards its attorneys' fees and related expenses.

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March 17, 2014

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I further certify that I caused copies of the foregoing document to be served on March 17, 2014 upon the following in the manner indicated:

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